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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Appl. No. : 09/914,603 Confirmation No.: 7928
Applicant : Nicholas Thomas
Filed : January 9, 2002
TC/A.U. : 1634
Examiner : Jeanine Anne Goldberg

Docket No. : PA9902
Customer No. : 22840

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

September 9, 2005

APPEAL BRIEF

Sir:

In response to the Notification of Non-Compliance with the Requirements of (37 CFR 1.192(c)) having the mailing date of August 31, 2005, Appellants submit this amended Appeal Brief in triplicate, appealing from the January 4, 2005, rejection of the Examiner, finally rejecting claims 1-13 and 15-17 in the captioned application. The Notice of Appeal was filed on May 6, 2005, which contained authorization to charge the “Appeal Fee” to Appellants’ Deposit Account. The Appeal Brief filed on June 30, 2005, was filed with a Transmittal of Appeal Brief (Large Entity), in duplicate, which contained authorization to charge the fee for filing the Appeal Brief to Appellants’ Deposit Account. Appellants do not believe any additional fees are required. However, Appellants’ hereby authorize the Commissioner to debit any fees due and credit any overcharges to Appellants’ Deposit Account No. 502-590.

Real Party in Interest

Amersham Pharmacia Biotech, Inc. and Amersham plc, co-owners of the captioned application, are the real parties in interest to this appeal.

Related Appeals and Interferences

There are no other appeals or interferences related to the instant appeal.

Status of Claims

Claims 1–13 and 15–17 are pending in the captioned application and are currently under examination and being finally rejected. Claims 1–13 and 15–17 are appealed and are reproduced in the Claims Appendix, attached hereto.

Status of Amendments

Appellants did not request any amendment after Examiner's final rejection of all claims.

Summary of Claimed Subject Matter

The instant invention relates to methods for detecting the differential expression or presence of two analytes, and more specifically to procedures which provide for rapid and efficient analysis of gene expression in biological systems. In particular, the invention provides a method of detecting and analyzing differences between nucleic acids

from two sources, which method comprises: (1) providing nucleic acids from two sources as labeled probes, wherein the nucleic acids from each source are labeled with a distinct marker; (2) forming a mixture of the labeled probes with pooled reagents wherein each reagent is a population of beads carrying a polynucleotide target, the target of one reagent being different from the target of another reagent, the beads of one reagent being distinguishable from the beads of another reagent; (3) incubating the mixture under conditions to promote specific hybridization between probes and targets; and, (4) analyzing beads in the mixture by flow cytometry.

Independent claim 1 and claims 2-13 and 15-17 depending thereon, are directed to the bead base nucleic acid analysis methods discussed by Appellants at page 3, line 22, through page 5, line 2, of the specification.

Grounds of Rejection to be Reviewed on Appeal

1. Whether claims 1-4, 6-13 and 15-17 are properly rejected under 35 U.S.C. § 102(e) as being anticipated by Beattie et al. (US Pat. 6,268,147, July 2001).
2. Whether claim 5 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Beattie et al. (US 6,268,147, July 2001) in view of Cocuzza et al. (US Pat. 5,484,701, January 1996).

Argument

1. **Claims 1-4, 6-13 and 15-17 are not properly rejected under 35 U.S.C. 102(e) § as being anticipated by Beattie et al. (US 6,268,147, July 2001).**

In a final office action dated January 4, 2005, the Examiner has rejected claims 1–4, 6-13 and 15-17 under 35 U.S.C. § 102(e) as being clearly anticipated by Beattie et al. (US 6,268,147, July 2001). Specifically, the Examiner states, “Beattie et al. (herein referred to as Beattie) teaches a method of nucleic acid analysis using tandem hybridization on color-coded microspheres and flow cytometric detections (Example 18)(limitations of Claim 14). Beattie teaches that the stacking hybridization approach is applicable to "bead technology" where different capture probe sequences are tethered to microspheres which are distinguishable by any measurable (detectable) unique physical or chemical property associated with each bead, such as size, shape, mass, spectral profile, chemical reactivity, electronic properties, etc (col. 38, lines 35-43)(limitations of Claim 8-12,16-17). Beattie teaches that the nucleic acid analyte is annealed with a labeled stacking probe of sequence and length designed to bind to a unique position within the analyte nucleic acid (col. 38, lines 60-64)”.

MPEP 2131 provides:

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

“The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Appellants respectfully submit that Examiner is of the opinion that since the claims are drawn to “comprising methods”, the claims do not exclude the use of stacking probes. Examiner is of the opinion that therefore the claims are anticipated. Appellants respectfully disagree. Appellants submit that while Appellants’ claims are drawn to “comprising methods” and could encompass additional elements, Beattie does not anticipate Appellants’ claims.

Appellants respectfully submit that Beattie clearly does not teach each and every limitation of the claims of the present invention. Furthermore, Beattie fails to disclose, teach or suggest the present invention. Beattie describes a method for nucleic acid analysis using tandem hybridization on color-coded microspheres and flow cytometric detection (Example 18, columns 38–40, Figure 15A and 15B). The method of Beattie requires hybridization of three molecules, (a) a labeled stacking probe, (b) a probe on the bead, and (c) a nucleic acid to be analyzed. The labeled stacking probe hybridizes in tandem with the probe on the bead to the nucleic acid molecules being analyzed. The hybridization product is then analyzed by flow cytometry and detection of label on the stacking probe (Figure 15A and 15B).

Appellants submit that Beattie fails to disclose a method comprising the step of “providing the nucleic acids from two sources as labeled probes” (claim 1 of the instant application). Beattie instead provides a labeled stacking probe, for the detection of the hybridization event. Beattie does not provide nucleic acids from two sources (or target in Beattie) as labeled probes. The current invention is therefore clearly distinct from Beattie.

In addition, Appellants direct the Examiner's attention to Figures 2, 3 and 4 of the instant application, as well as to Appellants' description that "mRNAs or cDNAs prepared from control and test cells or tissues are labeled with fluorescent tags to identify their source" (page 4, lines 20-21). It is clear that Beattie et al. does not teach a method comprising the step of "providing the nucleic acids from two sources as labeled probes" (claim 1 of the instant application). For this reason the rejection is improper.

In view of the foregoing, Appellants respectfully submit that the Examiner's rejection cannot be sustained and should be withdrawn.

2. *Claim 5 is not properly rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Beattie et al. (US 6,268,147, July 2001) in view of Cocuzza et al. (US Pat. 5,484,701, January 1996).*

The remaining issue is whether Appellants' claim 5 is rendered obvious over Beattie et al. in view of Cocuzza et al. (US 5,484,701), and thus are not patentable under 35 U.S.C. § 103(a).

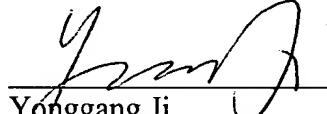
Appellants believe that the asserted references do not render obvious the Appellants' claim. As stated above, Appellants submit that there is a fundamental difference between the current invention and that of Beattie et al. As such, even if the references are combined, the combination does not render obvious Appellants' claim 5.

In view of the foregoing, Appellants respectfully submit that the Examiner's rejection cannot be sustained and should be withdrawn.

Conclusion

In view of the foregoing, Appellants respectfully assert that the Examiner's rejection cannot be sustained and respectfully requests the reversal of the rejection.

Respectfully submitted,

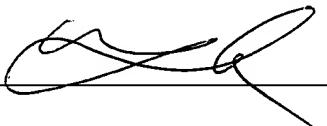


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CLAIMS APPENDIX

The Rejected Claims

Claim 1 (previously presented): A method of detecting and analyzing differences between nucleic acids from two sources, which method comprises:

- a. providing the nucleic acids from two sources as labeled probes wherein the nucleic acids from each source are labeled with a distinct marker;
- b. forming a mixture of the labeled probes with pooled reagents of at least two reagents wherein each of the pooled reagents comprises a population of beads carrying a polynucleotide target of known sequence, the polynucleotide target of any one of the pooled reagents being different from the target of any other of the pooled reagents and the beads of any one of the pooled reagents being distinguishable from the beads of any other of the pooled reagents by flow cytometry;
- c. incubating the mixture under conditions to promote specific hybridization between probes and targets; and
- d. analyzing beads in the mixture by flow cytometry to determine the identity of each bead and to quantify the relative abundance of each target sequence in the two sources.

Claim 2 (original): The method of claim 1 wherein the nucleic acids from two sources are mRNA or cDNA from cells or tissues.

Claim 3 (previously presented): The method of claim 1 wherein the polynucleotide targets are cDNA derived from cellular mRNA.

Claim 4 (previously presented): The method of claim 1 wherein the polynucleotide targets are PCR amplimers.

Claim 5 (previously presented): The method of claim 1 wherein the polynucleotide targets contain terminal biotin groups through which they are attached to streptavidin-coated beads.

Claim 6 (previously presented): The method of claim 1 wherein the polynucleotide targets are single-stranded nucleic acids.

Claim 7 (previously presented): The method of claim 1 wherein the nucleic acids are single-stranded nucleic acids.

Claim 8 (previously presented): The method of claim 1 wherein beads of one pooled reagent are distinguishable from beads of another pooled reagent by size.

Claim 9 (previously presented): The method of claim 1 wherein beads of one pooled reagent are distinguishable from beads of another pooled reagent by the nature of one or more markers attached to the beads.

Claim 10 (previously presented): The method of claim 1 wherein beads of one pooled reagent are distinguishable from beads of another pooled reagent by the concentration of one or more markers attached to the beads.

Claim 11 (previously presented): The method of claim 1 wherein beads of one pooled reagent are distinguishable from beads of another pooled reagent by the size and/or by the nature and the concentration of one or more markers attached to the beads.

Claim 12 (previously presented): The method of claim 9 wherein the markers are fluorescent markers attached to the beads.

Claim 13 (previously presented): The method of claim 1 wherein each of the nucleic acids is labelled with a fluorescent tag to indicate its source.

Claim 14 (cancelled)

Claim 15 (previously presented): The method of claim 1 further comprising the step of analysing the data obtained by flow cytometry to yield information about the relative and/or absolute abundances of individual nucleic acid sequences contained within the nucleic acids from two sources.

Claim 16 (previously presented): The method of claim 10 wherein the markers are fluorescent markers attached to the beads.

Claim 17 (previously presented): The method of claim 11 wherein the markers are fluorescent markers attached to the beads.

EVIDENCE APPENDIX

Applicants hereby append a copy of U.S. Patent 5,484,701 by Cocuzza and U.S. Patent 6,268,147 by Beattie. These are the evidence relied upon by the Examiner for rejection of appealed claims.

RELATED PROCEEDINGS APPENDIX

There are no other appeals or interferences related to the instant appeal.